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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,136

10/27/2003

Gerhard Bienhaus

18583-US1

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Roche Molecular Systems, Inc.  
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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/694,136	<b>Applicant(s)</b> BIENHAUS ET AL.	
	<b>Examiner</b> LORE RAMILLANO	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. In applicant's reply filed on 3/3/08, applicant amended claims 1, 2, 4-7. Claims 3, and 8-20 are cancelled. Claims 1, 2, and 4-7 are pending and are under examination.

### ***Response to Amendment***

2. Applicant should note that step (h) in claim 1 should have been underlined to indicate that such claim language was newly added to this claim.

### ***Claim Rejections - 35 USC § 112***

3. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, withdrawn.

### ***Prior art rejections***

4. The prior rejections Uematsu, Bienhaus, Acuff, Fujishiro, and Mochido are withdrawn in light of applicant's amendments. New rejections follow.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1 and 4-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujishiro et al. ("Fujishiro," US 5645723).

Fujishiro teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is

located in each of the matrix vessels to which the biological material to be purified binds, d) extracting the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels; and (h) closing the collecting unit with a closure unit. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

Fujishiro further teaches that the biological materials are added to the lysis vessels by only opening the lysis vessel into which material is to be added and the caps of the other lysis vessels of the lysis unit are closed and the caps of the matrix unit are in the leaned-to position before addition of the lysis liquids (i.e. p. fig. 7, col. 4, lines 20-46).

Fujishiro further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by

removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1, 2, and 4-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bienhaus et al. ("Bienhaus," WO 96/31781, translated by [www.worldlingo.com](http://www.worldlingo.com)) in view of Fujishiro.

Bienhaus teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are

enriched with biological material are collected in the collecting vessels; and (h) closing the collecting unit with a closure unit. (i.e. p. 6-8 of translation).

Bienhaus further teaches that the liquids in the matrix vessels are extracted by centrifugation and that the biological materials are added to the lysis vessels by only opening the lysis vessel into which material is to be added and the caps of the other lysis vessels of the lysis unit are closed. (i.e. p. 6-8 of translation).

Bienhaus further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. p. 6-8 of translation).

As to claim 5, Bienhaus does not specifically teach that the caps of the matrix unit are in the leaned-to position before addition of the lysis liquids.

The teachings of Fujishiro are indicated above. It would have been obvious to a person of ordinary skill in the art to modify Bienhaus by having caps in a leaned-to position because it would be beneficial to have a cap that is directly next to the vessel to allow the user to easily and quickly cover the vessels to prevent contamination.

***Response to Arguments***

8. Applicant's arguments, see p. 4-7, filed 3/3/08, with respect to the rejection(s) of claim(s) 1-7 under Uematsu, Acuff, and Mochido have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new ground(s) of rejection is made in view of Fujishiro and Bienhaus.

9. Applicant's arguments with respect to claims 1, 2, and 4-7, with regard to the rejections by Fujishiro and Bienhaus have been considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORE RAMILLANO whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-7420.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

Lore Ramillano  
Examiner  
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